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(71) Applicant (for all designated States except US): IMMUNO SWEDEN AB [SE/SE]; Råsundavägen 166, S-171 30 Solna (SE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): WALTHER, Bruno [SE/SE]; Sätesholms gård, S-240 33 Löberöd (SE). NILSSON, Billy [SE/SE]; Finnstugatan 30, S-595 00 Mjölby (SE).

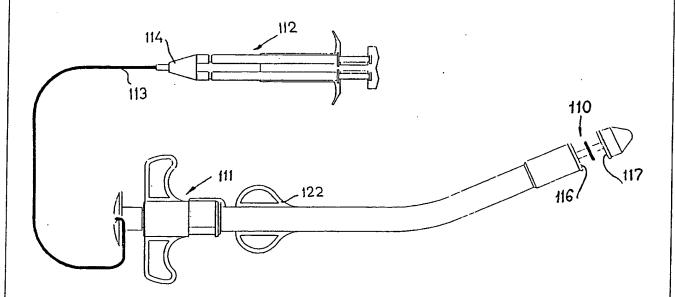
(74) Agent: MOBERG, Sture; Sture V Moberg AB, Kungstensgatan 48, S-113 59 Stockholm (SE).

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(54) Title: INSTRUMENT FOR ANASTOMOSIS



(57) Abstract

An instrument for anastomosis comprising means that permit folding of distal end portions of first and second tubular tissues over clamping surfaces (116, 117) on the instrument to form ring shaped flange portions for application of a bonding agent, and means for cloning up the clamping surfaces towards each other with the ring shaped surfaces lying therebetween. The instrument has means (112, 113, 114, 115) for admission of the bonding agent to the joint area through the instrument, preferably from the rearmost end and to the tip portion (110) of the instrument, preferably in the shape of a thin, flexible hose (113), which is passed through the instrument.

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#### INSTRUMENT FOR ANASTOMOSIS

The present invention relates to means and a method for surgical stitching together portions of body flesh, tissue, membranes, etc. In the present context the word stitching is used in its broadest meaning to define permanently affixing to each other or joining together of two or more portions of body flesh, tissue, membranes, etc.

The invention is a result of certain investigations in connection with anastomosis, and will be discussed below predominantly with reference had thereto, although the invention is by no means restricted only to that particular field.

In the past, surgical stitching operations for stitching together portions of body flesh, tissue, membranes, etc. were carried out while using various kinds of needles and threads to form stitched seams of sutures.

In modern surgical practice, it is known to use a stapler machine or device for inserting a series of U-shaped wire staples, such as of tantalum, into living tissue for the purpose of effecting a lengthwise "stitched" seam. Such staples are inert in the human body and, therefore, may permanently remain therein. Known surgical staplers, for example, are those disclosed in US-A-3.080.564, and US-A-3.494.533.

Surgical staplers, however, because of the delicate and critical circumstances of their use, must meet very high standards of reliability, effectiveness, and precision in operation, and these requirements necessarily have had to be met by relatively complex, carefully machined, and costly instruments. Among the requirements in a surgical stapler, for example, is that its parts be easily dismantable for sterilization purposes. A further requirement is that the staples be easily loadable into the device so that a single instrument may be reused successively during a surgical operation. Still another requirement is that the instrument functions easily and without danger of failure, for obvious reasons.

An obvious limitation or drawback which exists with prior known staplers resides in the mere fact that wire

Although wire staples, such as of tantalum, are considered to be inert in the human body, and for that reason are permitted to remain permanently therein, on application they have to penetrate the respective portions of body flesh, tissue, membranes, etc., and may, thus, give rise to leak pathes for bacteria etc. to move from one portion to another, or to move from one side of a tissue to the other side thereof. The same "penetration" considerations are valid also for ordinary sutures.

Accordingly, one of the objects of the present invention is to provide means for surgical stitching which is adapted to properly effect stitching together portions of live tissues, membranes, etc. without penetrating the same. Another object, in this regard, is to provide means for surgical stitching which is adapted to properly effect stitching together portions of live tissues, membranes, etc. without injurying the same.

Surgical operations are often performed under critical time limitations. These limitations require that all the means the surgeon may require for the operation are very readily available and may be used with a minimum of handling efforts, as well as in an extremely safe way. Accordingly, a further object of the present invention has been to provide means for use on surgical stitching which is adapted to permit a reliable stitching together of live tissues, membranes, etc. while minimizing all risks for residual problems.

A still further object of the invention has been to provide an instrument for anastomosis which is so simple and inexpensive to manufacture that it may be used as a disposable instrument.

Another object of the invention has been to provide an instrument for anastomosis which is easy to handle, and which may be handled in a very reliable manner.

Still another object of the inventin has been to provide an instrument for anastomosis which permits a simple and reliable application of a binding agent at the intended position within the anastomosis area.

A further object of the present invention has been to provide an instrument for anastomosis which has some built-in safety functions or features.

To the just mentioned end it is proposed, that the stitching together of live tissues, membranes, etc. should be carried out while

- a) holding at least two portions of live tissues on relatively movable carriers,
- b) applying a tissue adhesive on opposing surfaces of said tissues,
- c) moving said tissues together with said tissue adhesive disposed therebetween
- d) clamping said tissues together with an adequate clamping pressure,
- e) holding said tissues clamped together for a sufficient period of time to permit said tissue adhesive to bind,
  - f) releasing the clamping pressure, and
- g) cutting away superfluous tissue portions, if desired.

According to the invention, the tissue adhesive or bonding agent is preferably a two composite agent, advantageously an agent of the type sold by Immuno AG, Wienna, Austria, under the registered Trade Mark "TISSUECOL" or under the registered Trade Mark "TISSEEL".

One way of holding said at least two portions of live tissue, in the shape of tubular portions, on said relatively movable carriers according to the invention would be to slide end portions of said tubular portions on one carrier each, and tie them down on a central stem by means of one tobacco-pouch knot each.

An alternative way, according to the invention, would be to hook up said tubular end portions on opposing sets of hooks on said carriers.

According to the invention, one way of applying a tissue adhesive to the opposing surfaces of the tissues to be joined would be to apply the bonding agent manually, if desired by means of a double nozzled applicator means for a two composite bonding agent.

Alternatively, the two components of the two composite bonding agent could be housed in a shell or cover of a suitable shape, such as a ring-shaped shell, that is introduced between the opposing tissue surfaces before closing them together, and which is crushed or caused to open in any other way, as the two tissue surfaces are brought together, to thereby permit the bonding agent to emerge to cover said surfaces adequately.

Another way of disclosing the invention would be to describe it as a method of butt-joining the ends of two tubular tissue portions, in particular the ends of intestinal portions when realizing anastomosis, which method is characterized in that it is performed by the aid of a device comprising a first and a second carrier means for holding the ends of the two intestinal portions to be connected, which carrier means are movable relative to each other and are adapted to be moved from a spaced-apart position into an abutting position, wherein

the end of one of the tubular tissue portions is threaded onto the first carrier means and the end of the other tubular portion is threaded onto the second carrier means spaced apart from the first carrier means,

whereupon the ends of the two tubular tissue portions to be connected are temporarily constricted so as to form each an inwardly directed annular flange,

and whereupon the first and the second carrier means are moved towards each other to define a slight gap between the two constricted tubular tissue portions, preferably having a gap size of the order of 0.5 to 1.5 mm,

and whereupon further a tissue adhesive, preferably based on fibrinogen and Factor XIII, as well as a catalyst, based on thrombin, is introduced into the gap,

the first and the second carrier means are moved up at each other and are pressed together for a time sufficient to allow the tissue adhesive to solidify, and,

if desired, the tissue portions projecting inwards are cut off.

A particularly advantageous embodiment of an instrument for anastomosis for connecting first and second por-

tions of live tubular tissues with each other, comprising means permitting folding of outermost end portions of said first and second tubular tissues over clamping surfaces on the instrument to form opposing tissue surfaces or ring shaped flange portions for application of a binding agent and means for closing up said clamping surfaces towards each other with said ring shaped flange portions lying therebetween, is characterized, according to the present invention, essentially by means for admission of the binding agent to the connection area through the instrument, preferably from the rearmost end thereof to the tip portion of the instrument.

In this case, it is preferred that the said admission means comprise a thin, flexible hose which has, at the outermost end thereof, a connection means for connection of a binding agent applicator, and which passed entirely through the instrument, and which, at the innermost end thereof, is e.g. toroid shaped and provided with suitable outlet openings, e.g. slots.

It is also advantageous that an operating means for a clean cutting knife is interlocked to the admission hose for the binding agent in such a manner that operation of the clean cutting knife is possible only when the admission hose is at least partially retracted from its position for admission of the binding agent.

Further advantages and details of the present invention will become more evident from a consideration of the following descriptive text, when taken in conjunction with the appended drawing in which:

- FIG. 1 is a side view, partly in section, of two tubular tissue portion which are to be stitched together while using the illustrated tool;
- FIG. 2 is a side view, partly in section, of the two tubular tissue portions in a further step of the stitching operation;
- FIG. 3 illustrates a still further step of the stitching operation;
- FIG. 4 illustrates the completed stitching operation, and also shows the tool under withdrawal;

FIG. 5 is a schematic side view of another embodiment of an instrument for anastomosis according to the invention;

FIG. 6 is a plan view, from above, of the instrument in FIG. 5 where, however, the binding agent applicator has been omitted for clarity;

FIG. 7 - 10 illustrate the instrument for anastomosis according to the invention, partly in axial longitudinal section, in four different operation positions.

Referring now to the drawing in detail, a first embodiment of the tool or instrument according to the teachings of the present invention is depicted in FIGS. 1 to 4. As shown, the instrument comprises first and second carrier portions 10, 11, respectively, arranged on a common support and manipulating rod 12.

The instrument, generally denoted A, is adapted to be introduced into a first tubular tissue 13 through a first opening, which may be a wall opening or an end opening, and to be moved through said tissue 13 to such an extent, that the foremost end of the instrument protrudes from the first tubular tissue through a second opening 14 thereof. The instrument A is also adapted to be inserted into a second tubular tissue 15 through an end opening 16 thereof to position the first carrier portion 10 slightly inside the end opening 16.

With the instrument A introduced into the tissue portions as shown in FIG. 1, the tissue ends are folded down over the respective carrier portions 10, 11, and are secured in that position by means of tobacco-pouch knots 17, 18, as is illustrated in FIG. 2.

Then, the carrier portions 10, 11 are closed up towards each other to place the tissue end surfaces opposite each other, but still slightly spaced from each other. In that position a suitable bonding agent, such as a two composite bonding agent, is introduced between the opposing tissue surfaces to fill up the space therebetween as complete as possible, whereupon the carrier portions 10, 11 are closed up entirely to each other to clamp between them the tissue portions to be joined, and, of course, to

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press out any excess bonding agent between the surfaces. Naturally, the clamping force between the carriers should be adequate to hold the tissue portions in position, but still without causing undue injuries to the tissues.

In certain cases it may suffice to just withdraw the instrument A after completing the stitching operation, viz. in a direction opposite to the direction of introduction.

In other cases, it may be found desirable to cut away superfluous tissue material before extracting the tool. To that end the tool may be designed as a combined clamping tool and cutting tool, as is illustrated schematically in FIG. 4.

In FIG. 4 the tool has its first carrier portion 10 adapted bo be used also as an anvil in that it has a ring shaped anvil portion 21 arranged therein. carrier portion 11 is adapted to be used as a cutting tool in that it has arranged therein a ring shaped knife 22 which may be pushed forward against the anvil 21 to cut away excess tissue portions 23, (dough-nuts) and also any knot material, to trim the innermost edges of the united tissue ends.

It is contemplated that the tool may be provided with special means to hold the tissue end portions, such as pegs or hooks, and the opposing surfaces of the carrier portions 10, 11 may also be designed in a special way to contribute to a firm holding of the tissue ends, e.g. in that one surface has an axial, annular tongue adapted to enter into an annular groove in the opposing surface.

Instead of using a bonding agent in "free-flowing" state it has been contemplated to pack such agent in e.g. toroid-shaped tubes of a frangible material, which opens by itself under an adequate clamping force, to permit the bonding agent to flow out on the opposing tissue surfaces. In such a case, the opposing surfaces of the carrier portions may be adapted to first accomodate the bonding agent pack, and then to facilitate the collapsing of the package to permit the bonding agent to flow out.

A suitable bonding agent or "sealer" composition

might be a sealer protein solution comprising

85 mg Fibrinogen/ml

10 U FXIII/ml

3 mg Fibronectin/ml

3000 KIU Aprotinin

25 mg Human Albumin

The Thrombin Solution could comprise 500 or, alternatively, 4 U Thrombin/ml

40 umol CaCl<sub>2</sub>ml

The embodiment of the instrument for anastomosis according to the present invention as shown in FIG. 5 - 10 has a tip end, generally denoted 110, and a handle portion, generally denoted 111. In the embodiment shown the instrument comprises a bonding agent applicator, generally denoted 112, which may be of any known type. In the instant case the applicator 112 is devised for admission of a two component bonding agent, preferably of the kind which is sold by IMMUNO AG, Austria, under the registered Trade Mark "TISSUECOL" or under the registered Trade Mark

An important feature of the instrument for anastomosis according to the invention in this embodiment is the possibility to admit the bonding agent to the stitching area through the instrument, preferably all the way from the rear end of the handle portion 111 out to and through the tip portion. In the example this takes place in that a thin flexible hose 113 is passed from an adapter 114 for the applicator 112 through the rear end of the handle portion 111 and through the instrument to the tip end 110 where the hose in the example is formed into an almost entirely closed ring 115, disposed between two opposing anvil or clamping surfaces 116, 117, as is shown i FIGS. 5, 6, 7, and 8. The hose ring 115 is provided with suitable slots or other holes which serve as outlets for the bonding agent.

The hose 113 is comparatively rigid so that it may retain the toroid shape as shown in FIG. 6, but still it is flexible enough to permit withdrawal axially in its channel 118 for a purpose which will be disclosed in more

details below.

In the example the instrument has a replaceable tip cone 119 which may be easily replaced after depressing a locking button 120.

The instrument which preferably is slightly angled as shown in FIGS. 6 and 8 - 11, e.g. by an angle of about 30°, comprises an outer tube 121 which is provided with a handle 122, e.g. in the shape of two opposite tabs or loops. The handle end 111 comprises an operation grip 123 which is movable in relation to the outer tube 121 and is connected to the tip cone 119 to permit operation thereof in such a manner that the clamping surfaces 116, 117 may be closed up towards each other, FIG. 8 and 9. The movement of the operation grip 123 is controlled and locked by means of a latch 124 which is movable in a slot 125 in the outer tube. The latch may cooperate with stop means (not shown) which may on one hand permit feeling of various positions of the tip cone 119 and thus the distance of the clamping surfaces 116, 117 from each other, and on the other hand may lock the movement of the grip 123 in closing direction beyond a predetermined limit position, viz. to prevent squeezing injuries by an undue closing up of the surfaces 116, 117.

The handle portion 111 also comprises a an operation button 126 which over a flexible tube 127 is connected to ring knife 128 at the tip end 110 of the instrument. The ring knife 128 serves to cut off "dough-nuts" as is well known to those skilled in the art. Normally the button 126 is axially movable in relation to the reminder of the grip portion without causing any displacement of the tube 127 and thus of the knife 128. This is a safety fea-To permit the necessary movement of the knife 128 it is necessary for a pair of axially directed carrier fingers 129 within the button 126 to be pivoted apart from each other to engage with engagement surfaces 130, to permit axial displacement of the tube 127. This pivoting of the fingers apart from each other may be effected by means of a wedge member 131 secured to the hose 113, which wedge on withdrawal of the hose 113 enters at least partially between the fingers 129 and pivots these apart from each other. In this manner it is prevented that the ring knife 128 is pushed forwardly and possibly cuts off a portion of the hose 113 for the admission of the bonding agent, which portion might run the hazard of being left behind in the operation area.

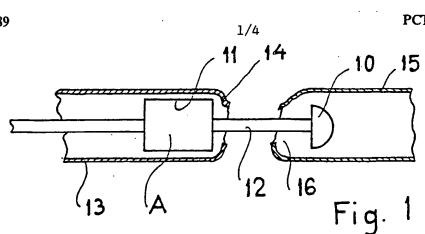
A number of modifications and alterations as to details may be carried out within the scope of the invention.

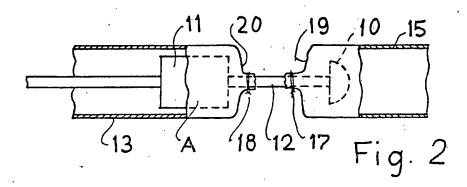
#### CLAIMS

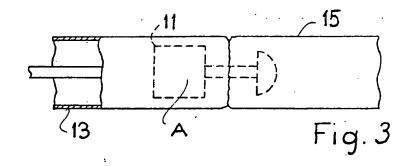
- 1. A device to be used for stitching together of live tissues, membranes, etc. characterized by comprising
- a) relatively movable carrier means for holding at least two portions of live tissue,
- b) means for momentarily holding said carrier means slightly spaced to permit applying a bonding agent on opposing surfaces of said tissues,
- c) means for moving said tissue carriers entirely together with said bonding agent disposed therebetween,
- d) means for clamping said tissues together with an adequate clamping pressure, and for holding said tissues clamped together for a sufficient period of time to permit said bonding agent to bind, and
- e) means for cutting away superfluous tissue portions, if desired.
- 2. A device to be used for stitching together first and second portions of live tubular tissue as claimed in claim 1 to form an anastomosis, characterized by comprising
- a) means adapted to permit folding outermost or distal end portions of said first and second tubular tissues over clamping surfaces on said clamping tool to form opposing tissue surfaces or annular flange portions to receive said bonding agent, and
- b) means for securing said folded distal end portions in position to permit application of said bonding agent and closing said clamping tool to complete the bonding cycle.
  - 3. A device as claimed in claim 1 or claim 2, characterized by means, such as annular, cooperating tongue and groove means, on said securing means to enhance holding of the distal tissue end portions.
  - 4. An instrument for anastomosis to be used for connecting first and second portions of live tubular tissues with each other, comprising means permitting folding of outermost end portions of said first and second tubular tissues over clamping surfaces (116, 117) on the instrument to form opposing tissue surfaces or ring shaped

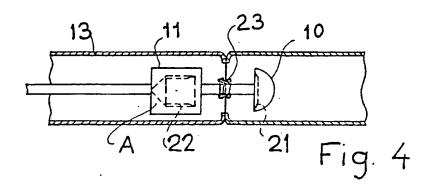
flange portions for application of a bonding agent and means for closing up said clamping surfaces (116, 117) towards each other with said ring shaped flange portions lying therebetween, characterized by means (112, 113, 114, 115) for admission of the bonding agent to the connection area through the instrument, preferably from the rearmost end thereof to the tip portion of the instrument.

- 5. An instrument as claimed in one or more of claims 1 4, characterized in that the said admission means comprise a thin, flexible hose (113) which has, at the outermost end thereof, a connection means (114) for connection of a bonding agent applicator (112), and which passed entirely through the instrument, and which, at the innermost end (115) thereof, is e.g. toroid shaped and provided with suitable outlet openings, e.g. slots.
- 6. An instrument as claimed in one or more of claims 1 5, characterized in that an operating means (126) for a clean cutting knife (128) is interlocked to the admission hose (113) for the bonding agent in such a manner that operation of the clean cutting knife is possible only when the admission hose (113) is at least partially retracted from its position for admission of the binding agent.
- 7. A frangible pack, preferably annular in shape, containing a tissue adhesive and preferably a catalyst, characterized in that the pack is adapted to be disposed as a unitary piece between the opposing tissue surfaces, and to be destroyed as said surfaces are clamped together to thereby let out the tissue adhesive and catalyst to complete a tissue joining operation.

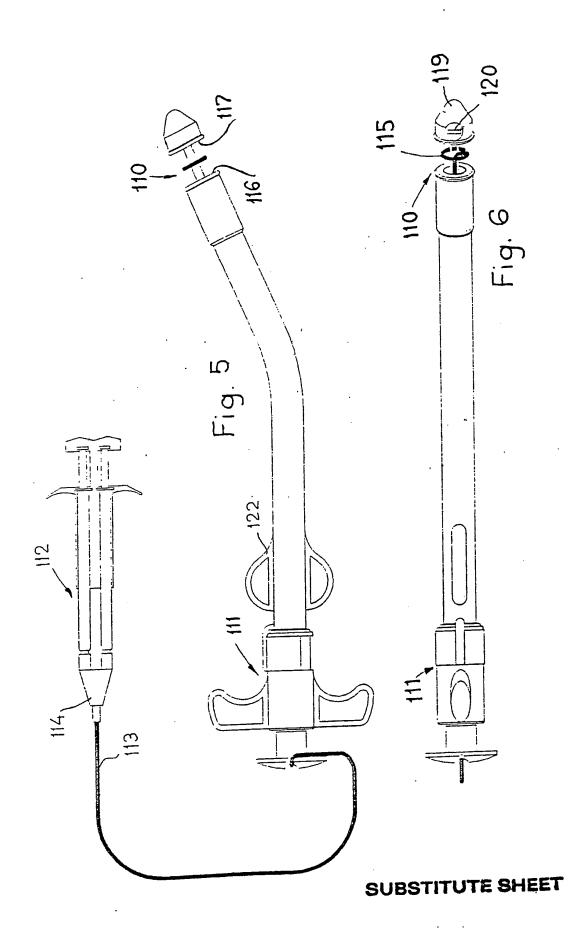




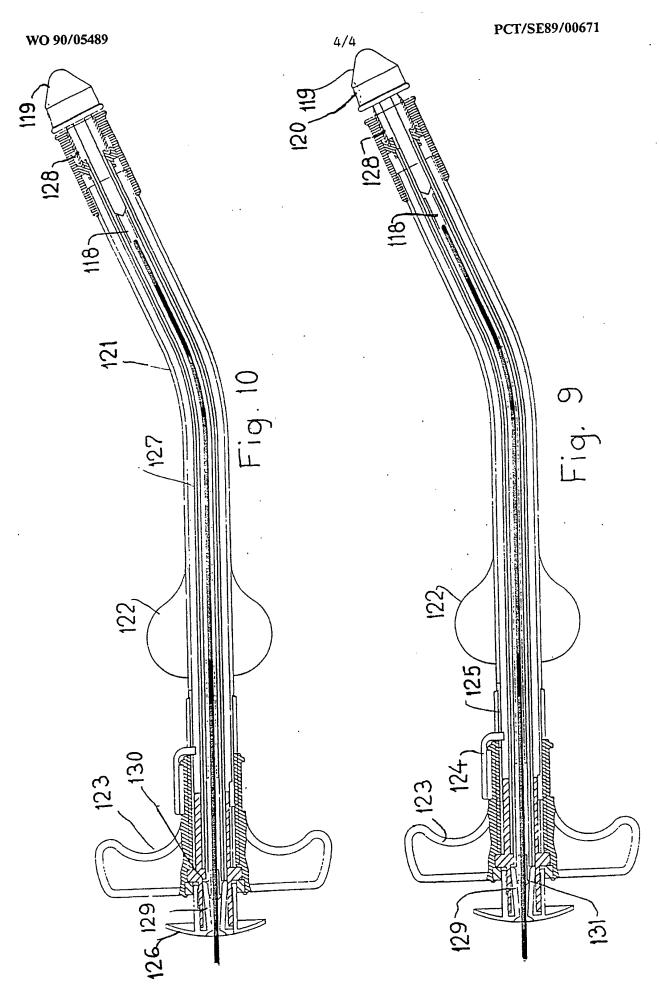




## SUBSTITUTE SHEET



## SUBSTITUTE SHEET



## SUBSTITUTE SHEET

#### INTERNATIONAL SEARCH REPORT

International Application No PCT/SE 89/00671

I. CLAS	SIFICATION OF SUBJECT MATTER (if several class	ification symbols apply, Indicate all) *	
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III. DOC	UMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of Document, 11 with Indication, where app	propriate, of the relevant passages 12	Relevant to Claim No. 13
Y	! SE, B, 435896 (SENCO PRODUCTS	INC.)	1-3,4
	29 October 1984, see abstr		:
	figures 1-14		1
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"P" document published prior to the international filing date but later than the priority date claimed "a" document member of the same patent family			
IV. CERT	TIFICATION		
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	SWEDISH PATENT OFFICE	Hans Peterson	1000

III. DOCU	MENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No	
A	DE, A, 2308496 (LINDORF) 22 August 1973, see figures 1-6; claims 1,7	1	
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A	Derwent's abstract, No. 83-774 986/39, SU 975 005, publ. week 8339 BODNARUK		
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FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET	
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V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE	
This international search report has not been established in respect of certain claims under Article 17(2) (a) for t	he following reasons:
1. Claim numbers	
Gami delibers , because inter relate to subject matter not required to be searched by this Author	·,,=, ·
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3. Claim numbers, because they are dependent claims and are not drafted in accordance with the secon	d and third sentences of
PCT Rule 6.4(a).	
VI.X OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING 2	
This international Searching Authority found multiple inventions in this international application as follows:	
1. A device according to claims 1-6	
2. A container according to claim 7	
1. As all required additional search fees were timely paid by the applicant, this international search report covers.	rs all searchable claims
of the international application,	
2. As only some of the required additional search fees were timely paid by the applicant, this international search fees were timely paid by the applicant, this international search fees were paid, specifically claims:	arch report covers only
3.X No required additional search fees were timely paid by the applicant. Consequently, this international search	h report is restricted to
the Invention first mentioned in the claims; it is covered by claim numbers: 1-6	
4. As all searchable claims could be searched without effort justifying an additional fee, the international Sear	rching Authority did not
invite payment of any additional fee.	
Remark on Protest	
The additional search fees were accompanied by applicant's protest.	
No protest accompanied the payment of additional search fees.	

## ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. PCT/SE 89/00671

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.

	Patent document d in search report	Publication date	Patent family member(s)	Publication date
SE-B-	435896	29/10/84	GB-A-B- 2016991 FR-A-B- 2420961 DE-A-C- 2851144 JP-A- 54128194 AU-D- 41364/78 US-A- 4207898 AU-A- 522691 CA-A- 1135141 SE-A- 781208	26/10/79 4 04/10/79 4 04/10/79 8 04/10/79 8 17/06/80 8 24/06/82 8 09/11/82
US-A-	3805793	23/04/74	NONE	
US-A-	3771526	13/11/73	NONE	
US-A-	3438374	15/04/69	NONE	
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